

**REMARKS****THE OBJECTIONS UNDER 35 USC 132(a).**

5 Applicants respectfully traverse the objections under 35 USC 132(a). There are three objections, namely: —

1) The original disclosure does not support the statement that the membrane optionally has a P<sub>10</sub> ratio, measured at pressure of 0.035 kg per square centimeter, over at least one 10° C. range between -5 and 15°C, of at least 1.3.

10 2) The original disclosure does not support the statement that the control sections may provide "at least the principal pathways and optionally", i.e. do not necessarily provide the substantially the only pathways for oxygen and carbon dioxide to enter or leave the packaging atmosphere.

15 3) "...deleting the limitation 'has a P<sub>10</sub> ratio, over at least one 10°C range between 5 and 15°C of at least 1.3' fails to support independent claim 1 that does comprise of the limitation".

These three objections will be considered in turn.

1. The objection that the original disclosure does not support the statement  
20 that the membrane optionally has a P<sub>10</sub> ratio, measured at pressure of 0.035 kg per square centimeter, over at least one 10° C. range between -5 and 15°C, of at least 1.3.

25 It is submitted that there is ample support in the specification as filed for the statement that the membrane optionally has a P<sub>10</sub> ratio, measured at pressure of 0.035 kg per square centimeter, over at least one 10° C. range between -5 and 15°C, of at least 1.3. Reference may be made, for example, to the following passages in the specification as filed.

30 a) Page 2, lines 15-22, of the specification as filed, immediately after the heading "Summary of the Invention" states (emphasis added)

*We have discovered, in accordance with this invention, that by forming thin polymeric coatings on microporous films, it is possible to create gas-permeable membranes which have novel and desirable combinations of O<sub>2</sub> permeability, change in O<sub>2</sub> permeability with temperature, and ratio of CO<sub>2</sub> permeability to O<sub>2</sub> permeability. Improved results can be obtained using a wide range of microporous base films and coating polymers. However, a particular advantage of the present invention is that it makes it possible to design packages which are tailored to the requirements of the particular respiring materials.*

This statement explicitly sets out the inventive discovery made by the applicants. It refers to any microporous film and any polymer. The statement does refer very generally to the change in O<sub>2</sub> permeability with temperature, i.e. but it does not state that the P<sub>10</sub> value should have any particular value. It places no limits on the P<sub>10</sub> value of the membrane. The statement is entirely consistent for example, with the membrane having a P<sub>10</sub> value below 1, about 1, or above 1,

b) Page 10, lines 10-15, of the specification as filed, which states (emphasis added)

*As discussed above, the properties of the membranes of the invention depend upon a number of factors, including the base film, the coating polymer, the coating composition, and the amount of coating composition applied to the base film. The membrane preferably has a P<sub>10</sub> ratio, over at least one 10°C range between -5 and 15°C, preferably over at least one 10°C range between 0°C and 15°C, of at least 1.3, preferably at least 2, particularly at least 2.5, especially at least 2.6.*

This passage states explicitly that a P<sub>10</sub> ratio of at least 1.3 is merely preferred, i.e. that such a P<sub>10</sub> ratio is not essential.

c) Page 5, lines 1-9, of the specification as filed, which states (emphasis added)

*The coating polymer should be selected so that the membrane has a desired  $P_{10}$  ratio and a desired  $R$  ratio, and should be coated onto the microporous film at a coating weight which results in a membrane having the desired balance between the permeability characteristics of the microporous film and of the coating polymer. For example, by choosing a crystalline coating polymer whose  $T_p$  is within or a little below an expected range of storage temperatures, it is possible to produce a membrane whose  $P_{10}$  is relatively large in the storage temperature range; furthermore, the size of the  $P_{10}$  ratio can be increased by increasing the  $\Delta H$  of the coating polymer.*

Again, this passage is not limited to any particular coating polymer or any particular  $P_{10}$  ratio. It also discloses (a) that in order to produce a membrane having a relatively large  $P_{10}$  ratio over a particular temperature range, one should select a crystalline coating polymer having a melting point ( $T_p$ ) within or a little below that temperature range; and (b) that the size of  $P_{10}$  ratio depends directly on the  $\Delta H$  (i.e. the heat of fusion) of the coating polymer. Although not explicitly so stated in the specification, it is of course well-known to polymer technologists that only crystalline polymers have melting points and that the heat of fusion of a crystalline polymer is a measure of its crystallinity.

d) Page 8, lines 17-23, on the specification as filed, which states (emphasis added)

*The coating polymer can be a single polymer or a mixture of two or more different polymers. Preferably the coating polymer is a crystalline polymer having a  $T_p$  of -5 to +40°C, particularly -5 to 15°C, especially 0 to 15°C, e.g. 1° to 15°C, and a  $\Delta H$  of at least 5 J/g, particularly at least 20 J/g. We have found that the higher the  $\Delta H$  of the polymer, the higher its  $P_{10}$  value over temperature ranges which include  $T_p$ . The  $T_p$  and  $T_o$*

*values of the polymer are preferably such that  $T_p - T_o$  is less than 10°C, particularly 5 to 10°C.*

This passage confirms the previous passage quoted above, in particular the relationship between the  $P_{10}$  ratio of the membrane and the crystallinity (if any) of the coating polymer. Furthermore, by stating that the coating polymer is preferably a crystalline polymer, this passage clearly discloses the possibility that the polymer is not a crystalline polymer, i.e. is an amorphous polymer.

(iv) Page 9, lines 7-12, of the specification as filed, which states (emphasis added)

*Other polymers which can be used include acrylate polymers (including methacrylate polymers) which are not SCC polymers, e.g. acrylate polymers which are derived from one or more monomers as specified in (ii) above; fluoropolymers (the term "fluoropolymer" being used herein to denote a polymer in which the atomic ratio of fluorine to carbon is at least 1.5, preferably at least 2); cis-polybutadiene; poly(4-methylpentene); polydimethyl siloxanes; ethylene-propylene rubbers; and polyurethanes.*

It is well-known that the "other polymers" listed above include polymers which are not crystalline, e.g. polydimethyl siloxanes and ethylenepropylene rubbers. It is clear from the passages quoted above, that membranes in which the coating polymer is not a crystalline polymer will have lower  $P_{10}$  ratios than membranes in which the coating polymer is a crystalline polymer (when the  $P_{10}$  ratio is measured by a 10°C temperature range which include the melting point of the crystalline polymer), for example a  $P_{10}$  ratio, measured at pressure of 0.035 kg per square centimeter, over at least one 10° C. range between -5 and 15°C, of at least 1.3.

2. The objection that the original disclosure does not support the statement that the control sections may provide "at least the principal pathways and optionally", i.e. do not necessarily provide substantially the only pathways for oxygen and carbon dioxide to enter or leave the packaging atmosphere.

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Page 2, lines 22-25, of the specification as filed, states (emphasis added).  
*As further discussed below, the gas-permeable membranes of this invention are generally used as control sections which provide the sole, or at least the principal, pathway for gases to enter or leave a sealed container containing a respiring material..*

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it is submitted, therefore, that there is clear basis for the statement that the control sections may provide "at least the principal pathways", i.e. do not necessarily provide substantially the only pathways" for oxygen and carbon dioxide to enter or leave the packaging atmosphere

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3. The objection that "deleting the limitation 'has a  $P_{10}$  ratio, over at least one 10°C range between 5 and 15°C of at least 1.3' fails to support independent claim 1 that does comprise of the limitation".

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The amended specification makes it clear that a  $P_{10}$  ratio, measured at pressure of 0.035 kg per square centimeter, over at least one 10° C. range between -5 and 15°C, of at least 1.3 is an optional feature of the invention. Independent claims 1, 20 and 29 include that optional feature as an essential feature of the claim. Independent claims 36, 48, 56, 66 and 72 do not require the presence of that optional feature. Applicants do not understand how reference, in the description, to the feature as optional can be said to fail to support independent claim 1 in the description. It is commonplace for patents to include independent claims of differing scopes, and in such circumstances, it is incorrect and misleading to refer to a feature which appears in some, but not all, independent claims, as essential. If the Examiner maintains this objection, she is asked to clarify the basis for it.

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## THE REJECTIONS UNDER 35 USC 112

Applicant respectfully traverses the rejection of claims 36-77 under 35 USC 112,

5 first paragraph, as

*based on a disclosure which is not enabling the deletion of a  $P_{10}$  ratio, over at least one 10°C range between 5 and 15°C of at least 1.3 which is critical or essential to the practice of the invention, but not included in the claims is not enabled by the disclosure. See In re Mayhew, 527 F.2 D 122 9, 188 USPQ 356 (CCPA 9776. The original specification has no support for the deletion of a  $P_{10}$  ratio of at least one 10°C range between 5 and 15°C of at least 1.3)"*

10 insofar as that rejection can be understood, for the following reasons.

Applicant submits that this rejection should be withdrawn for the reasons set out  
15 below. However, it is noted for the sake of completeness that the MPEP indicates that a rejection under 35 USC 112, first paragraph, based on failure to support a claim limitation, should be rejected as lacking adequate written description (see for example MPEP 2163.01); whereas a rejection based on the omission of an element which applicant describes as essential or critical should be rejected as lacking enablement  
20 (see for example MPEP 2164.08(c)). It is unclear which of these rejections is being made in the Office Action.

As set out in detail above, in the discussion of the objection under 37 CFR 1.132(a), the original specification makes it clear that there is basis in the original  
25 disclosure for claims that do not refer to a  $P_{10}$  ratio (i.e. which does not require a  $P_{10}$  ratio over at least one 10°C range between 5 and 15°C of at least 1.3), and that a  $P_{10}$  ratio as specified in claim 1 is not critical or essential to the invention, but rather is explicitly referred to as merely a preferred feature.

The Examiner, in paragraph 3, of the Office Action refers to the fact that a  $P_{10}$  ratio over at least one  $10^{\circ}\text{C}$  range between  $5$  and  $15^{\circ}\text{C}$  of at least  $1.3$  is disclosed as preferable and then states

*This excerpt does not give support that the  $P_{10}$  is optional; instead that it has other preferred  $P_{10}$  ratios.*

This comment seems to indicate (contrary, it would seem, to the objection and the rejection) that the Examiner recognizes that a  $P_{10}$  ratio as specified is **not** an essential part of the invention. This comment perhaps also indicates that, in the Examiner's opinion, the specification and claims should state explicitly that the gas-permeable membranes of the invention do have a  $P_{10}$  ratio, without specifying what that  $P_{10}$  ratio is, and that the membranes **optionally** have a  $P_{10}$  ratio as specified. Such a statement would not, however, add anything to, or subtract anything from, the present disclosure, since **every** gas-permeable membrane **inherently** has a  $P_{10}$  ratio over any specified  $10^{\circ}\text{C}$  range; depending upon the coating polymer and the temperature at which the measurement is made, the  $P_{10}$  ratio may be less than  $1$ , about  $1$ , or substantially greater than  $1$ .

Whatever the precise basis for this rejection, it is clear that the Examiner has not complied with the consistent direction in the MPEP that rejections under 35 USC 112 for lack of enablement or lack of written description must be accompanied by evidence or reasoning. For example, MPEP 2163.04 states that "the Examiner has the initial burden of presenting by a preponderance of evidence why a person skilled in the art would not recognize in an applicant's disclosure a description of the invention defined by the claims; and MPEP 2163 III A states that "in rejecting a claim the Examiner must set forth express findings of fact which support the lack of written description". Similar directions, in relation to rejections for lack of enablement, are provided by, for example, MPEP 2164.07 I B.

For the sake of completeness, Applicant also notes that those skilled in the art (a) would recognize in Applicant's original disclosure a description of the invention defined in all the claims, including in particular claims 36-77; and

(b) would have no difficulty in making and using the invention defined in all the claims, including in particular claims 36-77, using the information presented in the original disclosure; as the specification notes, on page 4, lines 4-6

... *the invention makes it possible to prepare novel membranes having very desirable permeability characteristics, and to achieve controlled variation of those characteristics.*

and on page 5, lines 11-13,

... *the invention makes it possible to produce membranes whose properties can be tailored, much more closely than is now possible, to the needs of a particular respiring biological material.*

### CONCLUSION

It is believed that this application is now in condition for allowance, and such action at an early date is earnestly requested. If, however, there are any outstanding issues that could usefully be discussed by telephone, the Examiner is asked to call the undersigned.

Respectfully submitted,



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